OCT - 1 2001

APPENDIX 6: 510 (K) SUMMARY

K011049

510(k) Summary
As required by 807.92
For ExpressSuite
Prepared on April 5, 2001

Submitted by: VIDAR Systems Corporation
460 Spring Park Place
Herndon, VA 20170
Telephone: 703-471-7070
Fax: 703-471-1165

Contact Person: Mary Harp
Software Product Manager, Medical Business Line

Device Trade Name: ExpressSuite

Common Name: Teleradiology, Digital Film Duplication Software

Classification: Image Digitizer (Accessory) Sec. 892.2030.

Predicate Device: Mitra Imaging, Inc. Film Express Scanning Software K970652

Manufactured by: VIDAR Systems Corporation, 460 Spring Park Place, Herndon, VA 20170

Description of Device: Teleradiology and Digital Film Duplication Software for use with Medical Image Digitizers.

Intended Use for the Device: ExpressSuite is indicated for forwarding a DICOM image from a Medical Image Digitizer to either a DICOM Print Class Provider or a Storage Class Provider. The target population is users wishing to use a medical film digitizer to scan analog or transmissive films to a DICOM workstation using a traditional Teleradiology approach and users wishing to making duplications of film prints using digital technology in DICOM and postscript protocols.

Substantial Equivalence to Predicate Device: ExpressSuite is substantially equivalent to Mitra Imaging, Inc. Film Express Scanning Software K970652 at 115 Randall Drive, Waterloo, Ontario, Canada N2V1C 5. Technical differences between this device (ClinicalExpress) and the predicate raise no new issues of safety and effectiveness.

TECHNICAL COMPARISON OF EXPRESSSUITE SOFTWARE

Attribute	**VIDAR ExpressSuite**	**Mitra FilmExpress*[ii]**
Operating System	Windows NT 4.0, Win 2000	Windows NT 4.0
Printing protocols	DICOM and Postscript	DICOM
Film Handling	Batch or single sheet	Batch or single sheet
Digitizers Supported	VIDAR DiagnosticPRO plus, VIDAR SIERRA plus	VIDAR DiagnosticPRO plus, VIDAR SIERRA plus, Lumisys 75, Howtek 450
Passowrd protection	2 levels – administrator and user log-on	2 levels – administrator and user log-on
Resolutions supported	75, 150, 300 dpi	75, 150, 300 dpi on VIDAR products
Bit depth supported	8 and 12 bit depth	8 and 12 bit depth
Number of copies selectable	1-9 copies selectable	1-9 selectable
Medium type	Selectable per DICOM standards	Selectable per DICOM standards
Preview image	yes	Yes
Film size selection	Selectable per DICOM standards	Selectable per DICOM standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Ms. Mary Harp
Product Manager,
Medical Software
VIDAR Systems Corporation
460 Spring Park Place
HERNDON VA 20170

Re: K011049
Trade/Device Name: ExpressSuite Image Digitizer Accessory
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical Image Digitizer
Regulatory Class: II
Product Code: 90 LMA
Dated: July 20, 2001
Received: July 23, 2001

Dear Ms. Harp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EXPRESSSUITE INDICATIONS FOR USE FORM

Ver/ 3 - 4/24/96
Applicant: VIDAR Systems Corporation
510(k) Number (if known): K011049
Device Name: ExpressSuite
Indications For Use:

ExpressSuite is indicated for forwarding a DICOM image from a Medical Image Digitizer to either a DICOM Print Class Provider or a Storage Class Provider. The target population is user's wishing to use a medical film digitizer to scan analog or transmissive films to a DICOM workstation using a traditional Teleradiology approach and users wishing to making duplications of film prints using digital technology in DICOM and postscript protocols.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011049

Prescription Use ✓